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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,145	08/04/2003	Chew Kiat Heng	NAA 0018 PA/41049.20	5097
7590	11/02/2005			
Killworth, Gottman, Hagan & Schaeff, L.L.P. Suite 500 One Dayton Centre Dayton, OH 45402-2023			EXAMINER WHALEY, PABLO S	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,145	HENG ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

ELECTION/RESTRICTIONS

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I: Claims 1-21 and 27 drawn to a method and computer readable medium for determining a statistical model for predicting disease risk for a member of a population, classified in class 702, subclass 127. If this Group is elected, then the below summarized specie election is also required. Also, if this Group is elected, then the below summarized specie election is also required.

Group II: Claim 22 drawn to a method of imputing missing data indicative of a plurality of factors, classified in class 702, subclass 127. If this Group is elected, then the below summarized specie election is also required. Also, if this Group is elected, then the below summarized specie election is also required.

Group III: Claims 23-26 drawn to a method of grouping a plurality of data sets into groups, classified in class 702, subclass 127. If this Group is elected, then the below summarized specie election is also required. Also, if this Group is elected, then the below summarized specie election is also required.

The inventions are distinct and divergent, each from the other because of the following reasons:

The inventions of **Groups I and Groups [II and III]** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they

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have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I and Groups [II and III] have different functions. Group I is drawn to a method and computer readable medium for determining a statistical model for predicting disease risk for a member of a population. Critical features of Group I that are distinct from Groups II and III include determining a plurality of weights and optimizing parameters of candidate models. Groups II and III do not disclose such limitations.

The inventions of **Group II and Groups [I and III]** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group II and Groups [I and III] have different functions. Group II is drawn to a method of imputing missing data indicative of a plurality of factors. Critical features of Group II that are distinct from Groups I and III include imputing missing data for factors in one batch at a time. Groups I and III do not disclose such limitations.

The inventions of **Group III and Groups [I and II]** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group III and Groups [I and II] have different functions. Group III is drawn to a method of grouping a plurality of data sets into groups. Critical features of Group III that are distinct from Groups I and II include performing recursive division on each data set group. Groups I and II do not disclose such limitations.

Thus, the search for the three groups together would present an undue search burden as they are directed to methods that are generally distinct and separate.

SPECIE ELECTION REQUIREMENT

This application contains claims directed to patentably distinct and divergent species of the claimed inventions. If Group I, II, or III is elected, the applicant is further required to make the following specie elections for purposes of examination. The applicant must elect one of the following species from Specie I (i.e. Specie I-A, I-B, or I-C) and one of the following species from Specie II (i.e. Specie II-A or II-B):

Specie I-A: Methods as set forth in Groups I, II, and III, wherein candidate model is a Cox proportional hazard regression model.

Specie I-B: Methods as set forth in Groups I, II, and III, wherein candidate model is a disease risk function of the form as indicated in Claim 11.

Specie I-C: Methods as set forth in Groups I, II, and III, wherein candidate model is neither a disease risk function nor a Cox proportional hazard regression model.

Specie II-A: Methods as set forth in Groups I, II, and III, wherein said set of characteristics comprises non-genetic factors.

Specie II-B: Methods as set forth in Groups I, II, and III, wherein said set of characteristics comprises genetic factors.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **Claims 1-9, 12-14, and 18-27** are generic to the above species. The candidate model species described above are distinct and divergent because they are drawn to mathematically distinct functions, and thus the bodies of literature that describe them are not

coextensive. Similarly, the bodies of literature that describe genetic factors (i.e. hair color, eye color, etc.) and non-genetic factors (i.e. family health history, age, smoking status, etc.) are not coextensive. Thus, the search for all species together would present an undue search burden as they are directed to separate divergent subject matter.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct and divergent, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Because these inventions are distinct and divergent for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the inventions to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am through 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 10/29/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER